

REMARKS

After entry of this amendment, claims 45 and 47-58 are pending. Applicants respectfully request entry of the above claim amendments as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct. Claims 47, 48, 51, 54 and 56-57 have been amended without prejudice or disclaimer to address the various points made in the Official Action. Support is found *inter alia* in the original claims. Claim 51 finds further support in the specification at page 13, lines 20-21 and page 15, lines 13-17. Claims 54 and 56-57 have been amended to place the claims in proper dependent form, support is found *inter alia* in the original claim. No new matter has been added.

Claim Objection

Claims 54 and 56-57 were objected to as being improper dependent form because the claims are directed to a product but depend from a method claim. In light of the above amendment, the rejection is believed to be rendered moot. Because the amendment corrects a problem noted by the Examiner and does not introduce any new issue, entry of this amendment is respectfully requested.

Rejections under 35 U.S.C. §112, Second Paragraph

Claims 47-48 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Claims 47-48 have been amended to clarify that the hemoglobin gene is from the plant species recited in the claims. No new issue has been introduced by this amendment. Entry of this amendment and reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112 , first paragraph

Claim 51 was rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree. However, to expedite prosecution, claim 51 has been amended without prejudice or disclaimer to recite the percent identity as 95%. The narrower scope of 95% identity to SEQ ID NO: 5 does not introduce any new matter or new issue so entry of this amendment is respectfully requested. Applicants submit that claim 51 as amended is believed to overcome both rejections.

Enablement

The Examiner asserts that the specification enables only SEQ ID NO: 5 and 6, but not any variants having less than 100% identity to SEQ ID NO: 5 and 6. The Examiner further argues that screening for substitutions or modifications is not routine and results of modifications are unpredictable, citing various references. Applicants respectfully disagree in view of the present amendment.

As discussed in the Response dated July 27, 2007, the specification provides detailed description including working examples on how to carry out the claimed method. Furthermore, the specification provides two examples of the hemoglobin that would lead a skilled person to conclude that the method as claimed is operable with any hemoglobin. In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claim without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)(routine screening of hybridomas was not “undue experimentation;” the involved experimentation can be considerable, so long as “routine”).

This analysis is in consistent with the Board decision in *Ex parte Kubin*, No. 2007-0819, slip op. at 14 (B.P.A.I. May 31, 2007)(hereinafter “*Kubin*,” available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd070819.pdf>), where the Board held that even a claim encompassing only 80% amino acid sequence identity to the disclosed sequence was fully enabled. *Kubin* at 15. As the Board noted in *Kubin*, even though practicing the full scope of the claims might have required extensive experimentation, the experimental techniques were well-known in the art, so the experimentation would have been routine and thus, not undue. *Id.* at 14.

As in *Kubin*, the experimentation required to practice the present claims is clearly not “undue.” Reconsideration and withdrawal of this rejection is respectfully requested.

Written Description

The Examiner alleges that the specification does not disclose a representative number of species encompassed by the claim. The Examiner further argues that the specification does not disclose any structural variant encompassed by the claim or provide sufficient relevant

identifying characteristics to allow one skilled in the art to identify variants. Applicants respectfully traverse.

The applicable test for written description is stated in the “Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, 1, Written Description Requirements” 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). As exemplified in Example 14 of the Guidelines, a claim reciting a protein having a specific sequence and variants with at least 95% identity to said sequence with a recited function was found adequately described. As amended, claim 51 now requires not only a sequence identity of 95%, but also that the transformed plant which expresses the hemoglobin produces an increased amount of storage reserves. In light of the amendment, Applicants submit that the claim satisfies the written description requirement.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 45 and 47-58 were rejected under 35 U.S.C. §103(a) as being obvious over Harper *et al.* (US 2002/0160378, hereinafter “Harper”), in view of Nykiforuk (US 6,552,250, hereinafter “Nykiforuk”), and further in view of Sowa (PNAS, 1998, 95: 10317-10321, hereinafter “Sowa”). Applicants respectfully disagree and traverse the rejection.

To support a conclusion of *prima facie* obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994).

The Examiner alleges that Harper teaches the production of starch and/or oil by growing a transformed plant that expresses at least one hemoglobin. Office Action at page 11. Applicants respectfully disagree with the Examiner’s characterization of this reference.

As disclosed in Harper’s specification, Harper teaches clusters of genes that are regulated in response to a stress condition in plants, such as plant polynucleotides whose expression is altered in response to stress conditions, and the production of transgenic plants expressing said polynucleotides. See paragraph [0011] of Harper. Although Harper discloses hemoglobin coding genes, Harper does not teach or suggest that expression of those genes in a plant would increase production of starch and/or oil. Thus, Harper teaches, at the most, a method of producing a transgenic plant comprising plant cells that exhibit altered responsiveness to at least

one stress condition as claimed in claim 29 of Harper. Harper does not, however, teach or suggest starch and/or oil production by expressing hemoglobin in a plant as alleged by the Examiner. Furthermore, it is respectfully submitted that, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. §103. *In re Antonie*, 559 F.2d 618, 619 (CCPA 1977). When the prior art does not reveal the property discovered by the applicant, as here, there is no basis to find obviousness. See *Id.*, at 620. Here, the “recovering” step specified in the claims would not have been obvious, since the prior art does not suggest that levels of starch and/or oil would be increased in the transformed plant.

The Examiner further argues that Sowa teaches a method for the production of a transformed plant expressing hemoglobin and growing said plant. Office Action at page 11. Applicants respectfully disagree.

As described at page 10318, Sowa transformed cultured maize cells with a barley hemoglobin gene. The entire experiment was conducted with the transformed cell lines alone. No maize plant was generated or grown. It is therefore respectfully submitted that Sowa does not teach the production of a transformed plant expressing hemoglobin and growing said plant as alleged by the Examiner. Furthermore, as noted by the Examiner, Sowa teaches that hemoglobin functions in plants to maintain the energy status of cells exposed to low oxygen environments. See Abstract at p. 10317. In fact, the entire reference discusses only this proposed hemoglobin function and provides evidence to support this suggestion. Nowhere in the reference is production of starch and oil discussed, either in corn or in the transformed maize cells. Applicants respectfully submit that Sowa, at the most, teaches or suggests only that hemoglobin may function in plants to increase survival in hypoxic acclimation. See page 10320, right Col., first paragraph. Because Sowa does not teach or suggest increased production of starch and/or oil by expressing hemoglobin in a plant, Sowa does not remedy the deficiency of Harper. Like with Harper, the “recovering” step is clearly not motivated.

The additional reference of Nykiforuk does not remedy the deficiencies of Harper and Sowa, alone or in combination. Nykiforuk is relied on by the Examiner as a supporting reference for disclosing a method of recovering oil from a transgenic plant which expresses a different transgene. Since Harper and Sowa, alone or in combination, do not teach or suggest production of starch and/or oil by expressing hemoglobin in a plant, the further combination of the

references with Nykiforuk would not remedy this deficiency and render the claimed method obvious.

Because all the limitations of claim 45 are not taught, claim 45 would not have been obvious to one skilled in the art over Harper, Sowa, and Nykiforuk, alone or in combination. Furthermore, if an independent claim is nonobvious then any claim dependent therefrom is nonobvious. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Claims 47-58 are dependent from claim 45, and are thus likewise nonobvious.

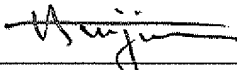
For the above reasons, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Conclusion

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a one-month extension of time to and including February 19, 2008 to respond to the Office Communication dated October 19, 2007 with the required fee authorization. No further fees are believed due. However, if any additional fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 13311-00008-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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